

## **REMARKS**

The only issues outstanding in the office action mailed April 3, 2009, are the rejections under 35 U.S.C. 112 and 103. The Examiner is thanked for indicating withdrawal of various previous rejections of record.

### **Rejections Under 35 U.S.C. 112**

Claims 5-8 have been rejected under 35 U.S.C. 112, second paragraph. It is argued, in this portion of the rejection, that claims 5 and 7 are dependent upon claim “41.” In fact, it is evident that the strikethrough in claim 4 is not readily visible, inasmuch as it is at the same height as the cross bar in the 4. Accordingly, claim 7 has been clarified (claim 5 is cancelled). The withdrawal of the rejection is accordingly respectfully requested.

Claim 26 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Reconsideration of this rejection is respectfully requested. Claim 26 recites a composition of claim 17, which is an “emulsifier-free emulsion.” It is argued, at page 2 of the office action, that an emulsifier-free emulsion is not clearly disclosed within the specification, as it is “difficult to determine what an emulsifier is.” Applicants disagree with this analysis. First, emulsifiers as such are well known to one of ordinary skill in the art, and simply saying that something is an “emulsifier” defines it adequately to one of ordinary skill. To the extent that it is argued, however, that an emulsifier-free composition is not taught by the recitation that the solutions and emulsions in the invention “can contain customary carriers such as solvents, solubilizers and emulsifiers, for example, water, ethanol, isopropynol, etc.,” Applicants disagree. It is well accepted that, where a specification gives support to claim a particular component, the specification equally gives support to exclude that component. See, for example, *In re Johnson*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977), and *Ex parte Graselli*, 231 USPQ 394 (POBA 1984, released 1986) *aff’d*. Reconsideration of this rejection is accordingly respectfully requested.

### **Rejections Under 35 U.S.C. 103**

Claims 1, 2, 5-10, 13-20, 22 and 24-27 have been rejected under 35 U.S.C. 103 over Heger '166 taken with Harivel '238. Reconsideration of this rejection is respectfully requested.

Heger, cited in the previous rejection, discloses aqueous dispersions of organic UV filters which are sparingly water-soluble or water-insoluble. The "UV filter substances" are a colloiddally disperse phase, which colloiddally disperse phase may exhibit a core/shell structure, where the core comprises the UV filter and the surrounding shell comprises a protective colloid ([0022]). Suitable polymers for this coating matrix are preferably water-soluble or water-swallowable, see paragraph [0025], disclosing gelatins such as Collagel A, *starch*, dextrin, or polymers based on neutral or ionic monomers such as ethylene oxide or lactic acid. Furthermore, in paragraph [0023] the purpose of this polymer shell is explained to be the stabilization of the particles in their colloiddal state from heterogeneous particle growth. The office action argues that the shell of the particle can be silica, citing paragraph [0127]. However, this paragraph refers not to the shell coating of the particle but to part of the process used to produce a dry powder from the light protection agent which has already been polymer-coated. See paragraph [0123]. Thus, the coating materials cited by the Examiner ([0127]) (e.g. silica) are not added until the process of spray or freeze drying (when the capsules already exist). This does not result in a capsule but rather in an amorphous silica structure. Furthermore, these coating agents favor the formation of agglomerates, whereas no single particles are obtained. Redispersion of the capsules (see paragraph [0129]) suggests that the capsules are released from the coating material. As a result, Heger does not teach silica as an encapsulating agent.

Instead, suitable organic polymers for the surrounding shell disclosed by Heger et al. (see above) differ strongly from inorganic silica. In addition, as described above, one of ordinary skill in the art would not have employed the coating agent cited in paragraph [0127] as a capsule matrix, instead using it to coat the previously encapsulated particles. In contrast to Heger et al., provides several advantages: The hydrophilicity of the walls of the capsules can be chosen irrespective of the solubility of the UV filter, the photostability of the filters is enhanced, the skin penetration and skin irritation of the UV filters can be suppressed and problems concerning the preparation (resulting from interactions between the components) can be avoided (see the present

application at paragraphs [0011] – [0015]. Furthermore, capsules are known to be sensitive to mechanical and strong thermal stress, which may result in the encapsulation breaking open and in release of the substances included therein. However, the present application enables structural conservation of the encapsulation, which is of great importance since the contact with the skin is to be avoided. It is not obvious that the structure of the capsules would be conserved during the process of spray- or freeze-drying and a person skilled in the art would not have considered encapsulating the UV filters which are to be obtained by spray- or freeze-drying. Without some indication that a silica coating would survive. Such indication, and thus motivation, is absent.

Similarly, the combination with Harivel would not have motivated one of ordinary skill in the art to encapsulate UV filters which are to be obtained by spray- or freeze-drying according to the present invention. Harivel does nothing to remedy the deficiencies of the primary reference. Harivel discloses foamable aqueous UV filter compositions such as sunscreens, which may be encapsulated. See page 11, lines 33-34. The capsule walls of such a formulation may preferably be made of silica (see page 12, lines 10-11) but Harivel fails to disclose spray or freeze-drying of the compositions in their preparation. One of ordinary skill in the art would not have found it obvious to spray or freeze-dry the compositions of Harivel, for example in the process of Heger, since the expectation would have been that the fragile silica would have been damaged.

Moreover, any suggestion of the obviousness of such combination is clearly rebutted by the advantages of the materials of the present invention. The indication in Heger that encapsulation of the UV filters stabilizes their colloidal state does not suggest to one of ordinary skill in the art that the present materials would possess the non-obvious advantage of easy ability of selection of the hydrophilicity of capsule walls, a respective of the solubility of the UV filter, and increased photostability of the filters, with skin penetration and skin irritation thereof being suppressed. Accordingly, it is submitted that this combination of references fails to suggest the presently claimed materials. Withdrawal of the rejection is accordingly respectfully requested.

Claim 21 has been rejected under 35 U.S.C. 103 over Heger, Harivel and Herzog '540. Reconsideration of this rejection is also respectfully requested. Herzog is cited solely for its disclosure of a self-tanning agent, and does not remedy the deficiencies of the above-noted references. Accordingly, withdrawal of this rejection is also respectfully requested.

Claim 23 has been rejected over Heger, Harivel and Chaudhuri '906. Reconsideration of this rejection is also respectfully requested. Chaudhuri is cited solely for its teaching of a photostabilizer. This reference does nothing to remedy the above-noted deficiencies of the previously cited references, and withdrawal of this rejection is also respectfully requested.

The claims are submitted to be in condition for allowance. However, if the Examiner has any questions or comments, she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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